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10/582,712	02/02/2007	Eran Eilat	EILAT3	7541

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EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,712	EILAT, ERAN	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *09/20/10*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *82-91* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *82-91* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/20/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the Amendments, Remarks and an IDS filed on 09/20/10. Claims 24, 29, 40, 43, 45, 54, 64-81 were cancelled and new claims 82-91 were added. Accordingly, claims **82-91** are pending and under examination.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the **first paragraph** of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims **84 and 90** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not disclose "a pipe that extends from the container and allows access of the foam or mousse to the ear". Applicant has not identified a support for the cited limitation in the specification and Examiner finds no support. This is a new

matter rejection.

The following is a quotation of the **second paragraph** of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims **85-86, 88 and 91** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim **85** recites the limitation "said dispensing device" in line 2. There is insufficient antecedent basis for this limitation in the claim. The claim depends on claim 82 which does not recite a dispensing device.

Claim **86** recites the limitation "the at least one" in line 2. There is insufficient antecedent basis for this limitation in the claim. The claim depends on claim 82 which does not recite "at least one pharmaceutically active".

Claim **88** recites the limitation "the at least one" in line 2. There is insufficient antecedent basis for this limitation in the claim. The claim depends on claim 82 which does not recite "at least one pharmaceutically active".

Claim **91** recites the limitation "the dispensing device in accordance with claim 89" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Claim 89 is a method claim and does not recite a device.

For examination purposes, it is interpreted that claim 91 depends on claim 90. However corrections are required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 90-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Cortifoam®, Drug information by Drugs.com, as evidenced by Cortifoam®, Physicians Desk Reference, 1995 edition.

Cortifoam® is a foam composition comprising hydrocortisone acetate stored in a container of a device that is suitable for administering foam formulations. The device contains a pipe that extends from the container (see the document, especially diagrams in page 10.

The intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Here, the limitation "for dispensing medication to the ear" is an intended use limitation.

The document is obtained on line on 11/9/10 and does not provide a date, however as evidenced by PDR 1995, Cortifoam® has been marketed for many years and well before 12/12/03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 82-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Purwar et al (5,843,930) in view of Cortifoam®.

Purwar et al teach a method of treating otitis by introducing an **antibacterially-**effective amount of a composition comprising a non-toxic, topical, otic pharmaceutical composition comprising, ciprofloxacin, a non-ionic viscosity augmenter, preservative, water, **hydrocortisone**, lecithin and a polysorbate 20-80 (see abstract and Summary). The formulations also comprise acetic acid in an amount sufficient to buffer the composition (col. 2, lines 65-68 and col. 4, lines 59-68).

An example of a formulation for delivering to the ear comprising ciprofloxacin HCL, water, glycerin, polysorbate 20 and other adjuvants is disclosed in Table 1.

Purwar lacks disclosure on the formulations being in the form of a foam and the device. However such deficiencies are cured by Cortifoam®.

Cortifoam® is a **foam** composition comprising **hydrocortisone** acetate stored in a container of a device that is suitable for administering foam formulations. The **device** contains a pipe that extends from the container (see the document, especially diagrams in page 10.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Purwar et al and Cortifoam® with a reasonable expectation of successfully preparing a foam formulation for the easy delivery of an active agent topically to the desired site. Purwar teach administration of formulations comprising active agents to the ear canal to treat ear disorders such as otitis, and Cortifoam® discloses a device holding and delivering a foam formulation

comprising active agents to a body cavity. It would have been obvious to one of ordinary skill in the art to implement the foam formulations and the device of Cortifoam® in the formulations and methods of treatment as disclosed by Purwar because it is disclosed that foams are a suitable dosage form for medicaments and they provide a longer lasting effect. It would have been obvious because the combination of the two references would have lead one of ordinary skill in the art to the claimed invention. It has been held that "when an application simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S,Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent application claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is... a person of ordinary creativity, not an automaton." Id. at 1742.

Claims 82-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Purwar et al (5,843,930) in view of Abram (US 6,730,288).

Purwar et al teach a method of treating otitis by introducing an **antibacterially-**effective amount of a composition comprising a non-toxic, topical, otic pharmaceutical composition comprising, ciprofloxacin, a non-ionic viscosity augmenter, preservative, water, **hydrocortisone**, lecithin and a polysorbate 20-80 (see abstract and Summary). The formulations also comprise acetic acid in an amount sufficient to buffer the composition (col. 2, lines 65-68 and col. 4, lines 59-68).

An example of a formulation for delivering to the ear comprising ciprofloxacin HCL, water, glycerin, polysorbate 20 and other adjuvants is disclosed in Table 1.

Purwar lacks disclosure on the formulations being in the form of a foam and the device. However such deficiencies are cured by Abram.

Abram teach a pharmaceutical **aerosol foam** composition including an effective amount of a pharmaceutically active ingredient, an occlusive agent, an aqueous solvent, an organic cosolvent, the pharmaceutically active ingredient being insoluble in both water and occlusive agent (se abstract and col. 1, lines 43-59).

It is disclosed that various aerosol and non-aerosol quick breaking and slow breaking foams for the topical delivery of pharmaceutical active ingredients are known in the prior art. In particular, the foam composition is an aqueous emulsion system. The foam composition upon actuation produces a stabilised, homogeneous, expandable foam which breaks easily with shear. A composition of this type is often referred to as an aerosol foam or "mousse" (see column 1, lines 4-12).

Abram discloses that suitable active agents include analgesics, antifungals, **antibacterials,** anesthetics, antivirals, anti-inflammatories, steroids, etc (see paragraph bridging columns 1 and 2). The pharmaceutical aerosol foam composition may include an effective amount of a propellant such as hydrocarbons, HFCs, nitrogen, etc. The propellant may be introduced into the mousse composition at the time of filling utilising for example a standard aerosol dispenser, e.g. a spray can arrangement (see col. 2, lines 23-35). The mousse formulations may contain an occlusive agent selected from mineral oils and greases, animal fats and greases, vegetable fats and greases, etc. preferred occlusive agent is petrolatum. The formulation may contain an effective amount of an emulsifier and/or surfactant. Abram further teaches that an aqueous solvent may be present in an amount of from 25% to 95% by weight based on the total weight of the composition (see col. 3, line 46 to col. 4, line 12).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Purwar et al and Abram with a reasonable expectation of successfully preparing a foam formulation for the easy delivery of an active agent topically. While Purwar does not specifically teach administration of the foam formulation comprising the active agent to the ear canal, it would have been obvious to one of ordinary skill in the art to deduce such from the combined teachings because Purwar discloses topical formulations comprising an active agent delivered to the ear canal and Abram teaches foam formulations comprising an active agent delivered topically. It would have been obvious because the

combination of the two references would have lead one of ordinary skill in the art to the claimed invention. It has been held that "when an application simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S,Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent application claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is... a person of ordinary creativity, not an automaton." Id. at 1742.

Although neither references teach a dispensing device containing a pipe extended from the container, Abram teaches a spray device for delivering its foam formulations. Thus, it would have been obvious to one of ordinary skill in the art to employ a suitable delivery device or to modify the device to adjust for ear canal delivery.

Also while Purwar does not specifically teach that the formulation is administered once or twice a day, dosing is well within the capabilities of one of ordinary skill in the art making the claimed invention.

Claims 82-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein (US 4,305,936) in view of Purwar et al (5,843,930).

Klein teach topical or local application comprising at least one corticosteroid, from about 1 to 4% by weight of solubilization agents consisting essentially of a combination of at least one glyceryl ester of a fatty acid of 6 to 22 carbon atoms and a betaine surfactant, from about 10% to 50% by weight of a composition of an alkanol cosolvent, and from about 20% to 50% water (see abstract and col. 2, lines 13-27). It is disclosed that local application means use in **body cavities** such as vaginal, nasal, **etc** (col. 1, lines 48-50). Klein also discloses a new topical or local preparation which can produce a foam when packaged either in the form of an aerosol or a non-aerosol **foam-forming** closure system (see col. 2, lines 7-10). Klein also disclose that propellants such as liquefied gases, nitrogen, propane, etc are employed in preparing aerosols (see col. 6, lines 6-11). Klein lacks disclosure on a method of treating ear disorders and a device comprising a container and a pipe. This deficiency is cured by Purwar et al.

Purwar et al teach a method of treating otitis by introducing an antibacterially-effective amount of a composition comprising a non-toxic, topical, otic pharmaceutical composition comprising, ciprofloxacin, a non-ionic viscosity augmenter, preservative, water, hydrocortisone, lecithin and a polysorbate 20-80 (see abstract and Summary). The formulations also comprise acetic acid in an amount sufficient to buffer the composition (col. 2, lines 65-68 and col. 4, lines 59-68).

An example of a formulation for delivering to the ear comprising ciprofloxacin HCL, water, glycerin, polysorbate 20 and other adjuvants is disclosed in Table 1.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Klein and Purwar et al with a reasonable expectation of successfully preparing a foam formulation for the easy delivery of an active agent topically. While Klein does not specifically teach administration of the foam formulation comprising the active agent to the ear canal, it would have been obvious to one of ordinary skill in the art to deduce such from the combined teachings because Klein teaches foam formulations comprising an active agent delivered topically and locally to body cavities, and Purwar discloses topical formulations comprising an active agent delivered to the ear canal. It would have been obvious because the combination of the two references would have lead one of ordinary skill in the art to the claimed invention. It has been held that "when an application simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S,Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent application claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not

seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is... a person of ordinary creativity, not an automaton." Id. at 1742.

Although neither references teach a dispensing device containing an extension, Klein teaches a spray device for delivering its foam formulations. Thus, it would have been obvious to one of ordinary skill in the art to employ a suitable delivery device or to modify the device to adjust for ear canal delivery.

Also while Purwar does not specifically teach that the formulation is administered once or twice a day, dosing is well within the capabilities of one of ordinary skill in the art making the claimed invention.

Response to Arguments

Applicant's arguments with respect to claims 24, 29, 40, 43, 45, 54, 64-81 have been considered but are moot in view of the new ground(s) of rejection.

Claims 82-91 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is (571)272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mina Haghighatian/

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